510(k) Summary
Safety ad Effectiveness Data Summary

MAY 15 2009

Prepared By:	Pluromed Inc. 25-H Olympia Avenue Woburn, MA 01801
Telephone Number:	781- 932-0574
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Contact Person:	James Wilkie jwilkie@pluromed.com

Proprietary Name:	BackStop Catheter
Classification Name:	Urological Catheters and Accessories
Common Name:	Urological Catheter
Classification:	Class II
Regulation Number:	876.5130
Product Code:	78 KOD
Indications for Use:	The BackStop Catheter is indicated for use by physicians for facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the injection of fluid into the urinary tract.
Performance Standards:	Recognition Number 14-193: AAMI / ANSI / ISO 11607-1:2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, 3ed. Recognition Number 2-98: AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing. Recognition Number 14-224: AAMI / ANSI / ISO 11137-1:2006, Sterilization of health care

products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.

Recognition Number 14-225: AAMI / ANSI / ISO 11137-2:2006, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

Substantial Equivalence:

Imager II Urology Torque Catheter
Urological Catheter
510(k) Number: 011965

Description of Device:

The BackStop Catheter is a 100cm, 3F single lumen radiopaque catheter to facilitate access to the urinary tract. The catheter is inserted over a guidewire or through the working channel of an ureteroscope and is progressed through the urinary tract to the desired ureter location. Once in place fluid may be injected via the catheter.

The device is a single lumen catheter with a stainless steel braid and a standard female luer lock hub on the proximal end.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Mr. James Wilkie
Vice President, Operations
Pluromed, Inc.
25-H Olympia Avenue
WOBURN MA 01801

Re: K090270
Trade/Device Name: BackStop Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KOD
Dated: May 4, 2009
Received: May 6, 2009

Dear Mr. Wilkie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

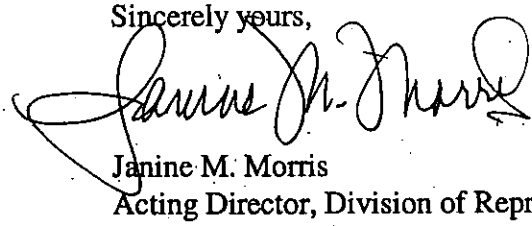
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090270

Device Name: BackStop Catheter

Indications for Use:

The BackStop Catheter is indicated for use by physicians for facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the injection of fluid into the urinary tract.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X	AND/OR	Over the Counter Use __
(21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090270